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Docket No.: 03108/0201123-US0

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Yenamandra Venkateswarlu et al.

Application No.: 10/814,777

Confirmation No.: 4938

Filed: March 30, 2004

Art Unit: 1625

For: BETA - CARBOLINE DERIVED GUANIDINE

ALKALOIDS, TIRUCHENDURAMINE

Examiner: R. J. Desai

## RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In the Office Action dated April 18, 2006, the Examiner has required restriction to one of the following invention groups:

- I. Claims 1, 2, 11-14, and 20-23, drawn to compounds and pharmaceutical compositions of the compounds given in claim 1;
  - II. Claims 3-10 and 24-37, drawn to a process of making the compounds;
- III. Claims 15, 16, and 47, drawn to a complex composition of the compound according to claim 1 and another therapeutic agent; or
  - IV. Claims 17-19 and 38-46, drawn to a method of treating a mammal.

Applicants hereby elect invention Group I (claims 1, 2, 11-14, and 20-23) with traverse. Although this election is made to be fully responsive, Applicants respectfully traverse the Requirement and reserve the right to petition under 37 C.F.R. § 1.144.

Invention groups I and II are related as a product and the process of making the product. The inventions are distinct if either (1) the process as claimed is not obvious and can be used to make another and materially different product or (2) the product as claimed can be made by another and materially different process. MPEP § 806.05(f).

To the extent that the Examiner contends that the claimed process can be used to make a materially different product, such a contention cannot stand. The process claims are explicitly limited to making the same product as claimed in the product claims. Furthermore, the process claims require extraction from an ascidian, whereas the product claims are limited to the product isolated from an ascidian species. The Examiner has not put forward any evidence or theory for isolating the claimed product from the claimed source by different means.

Similarly, a position that the claimed product can be made by a materially different process must also fail. The product claims are limited to product isolated from the ascidian *Synoicum macroglossum*. The process claims require materially the same process, subjecting an ascidian to solvent extraction.

The Examiner's remark that "\(\beta\)-carboline derivatives are known compounds and can be made by other processes" (Office Action at page 2) is inapposite, as no evidence or hypothesis has been put forward as to how this would be accomplished from the same ascidian species or from any ascidian species without use of extraction. Chemical syntheses are excluded from the claims.

Moreover, according to the Patent Office's examining procedures, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." MPEP § 803. Each of the claims recites tiruchenduramine of Formula 1, a novel compound, and derivatives thereof. Electing the invention group I drawn to the product, as Applicants have done, will require the Examiner to search the prior art for any disclosure of the claimed product, which includes art drawn to processes of making and using the product. Therefore, Applicants submit that

the claim groups identified by the Examiner do not warrant separate search and examination and the entire application can be examined without increasing the burden on the Examiner.

For these reasons, withdrawal of the Restriction Requirement is respectfully requested.

Applicants believe the application is in condition for allowance and respectfully request prompt and favorable action on the merits.

A petition for a two-month extension of time and a check in the amount of the required fee are enclosed to extend the period for response to July 18, 2006.

Dated: July 7, 2006

Respectfully submitted,

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Docket No. AMENDMENT TRANSMITTAL LETTER 03108/0201123-US0 Application No. Filing Date Examiner Art Unit R. J. Desai 1625 10/814,777-Conf. #4938 March 30, 2004 Applicant(s): Yenamandra Venkateswarlu et al. Invention: BETA - CARBOLINE DERIVED GUANIDINE ALKALOIDS, TIRUCHENDURAMINE TO THE COMMISSIONER FOR PATENTS Transmitted herewith is an amendment in the above-identified application. The fee has been calculated and is transmitted as shown below. **CLAIMS AS AMENDED** Claims Highest Number Remaining Number Previously After **Extra Claims** Amendment Paid Present Rate **Total Claims** 47 47 X Independent 6 9 X Claims Multiple Dependent Claims (check if applicable) 450.00 Other fee (please specify): Extension for response within second month 450.00 TOTAL ADDITIONAL FEE FOR THIS AMENDMENT: x Large Entity Small Entity No additional fee is required for this amendment. 04-0100 Please charge Deposit Account No. in the amount of \$ A duplicate copy of this sheet is enclosed. 450.00 X A check in the amount of \$ to cover the filing fee is enclosed. Payment by credit card. Form PTO-2038 is attached. 04-0100 x The Director is hereby authorized to charge and credit Deposit Account No. as described below. A duplicate copy of this sheet is enclosed. x Credit any overpayment. Charge any additional filing or application processing fees required under 37 CFR 1.16 and 1.17. July 7, 2006 Dated: Adda C. Gogoris Attorney/Agent Reg. No.: 29,714 DARBY & DARBY P.C. P.O. Box 5257 New York, New York 10150-5257 (212) 527-7727



Application No. (if known): 10/814,777

Attorney Docket No.: 03108/0201123-US0

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July 7, 2006

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Amendment Transmittal (1 page)

Petition for Extension of Time of Two months (1 page) Response to Restriction Requirement (3 pages)
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